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LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

EXAMINER

NOBLE, MARCIA STEPHENS

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,457

Applicant(s)

CRYSTAL ET AL.

Examiner

Marcia S. Noble

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.135(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.702(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-21 and 42-57 is/are pending in the application.
- 4a) Of the above claim(s) 2, 3, 11, 12 and 42-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-10 and 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SI/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/27/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-3, 6-21, and 42-57 are pending. Claims 11 and 12 are withdrawn, claims 4, 5, and 22-41 are canceled, claims 42-57 are new, and claims 1-3 and 20 are amended by Applicants response, filed 8/21/2006.

Election/Restrictions

2. Amended claim 2, 3, and newly submitted claims 42-57 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally elected invention was drawn to Group II, a gene transfer vector comprising a nucleic acid sequence encoding an immunogenic portion of an exotoxin of anthrax where the vector is a viral vector, and with species elections to the exotoxin, protective antigen (PA) and a subcellular sorting pathway being a lysosomal pathway. This is distinctly different from a gene transfer vector that further comprises a nucleic acid encodes an edema factor and lethal factor as claimed in amended claims 2 and 3. The invention is distinct from the inventions of claims 2 and 3 because they are drawn to two different nucleic acids that encode for structurally and functionally different proteins. The invention of new claims 42-57 is drawn to a method of producing an immune response against anthrax in a host. These claims depend upon the use of the gene transfer vector of claim 1. However, only a subcombination of the vectors encompassed by claim 1 would function in the method of claims 42-57. Claim 1 is

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broadly drawn to a nucleic acid and a heterologous sorting sequence with no requirements for a promoter or elements necessary for function in the method of claims 42-57. The elected invention is related to the instant method of 42-57 because the subcombination gene transfer vector that comprise elements necessary for expression of the elected invention can be use in this method. However other gene transfer vectors encoding different anthrax factors can be used with the method of 42-47 and the transfer vector of the elected invention can be used in other methods such as transfecting cells. Therefore, the inventions of claims 2 and 3 and the method of 42-47 are distinct from the elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 2 , 3, and 42-57 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 6-10, and 13-21 are under consideration.

Specification

2. The disclosure, objected to because of a hyperlink present in the specification on p 26 [0071], has been amended to delete the hyperlink. Therefore the objection is withdrawn.

NEW Claim Objections

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3. Claim 7 encompasses non-elected subject matter. The claim should be amended to only encompass elected subject matter.

NEW Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Amended claim 20 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 15. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Amended claim 20 now encompasses the transfer vector of claim 1 where in the gene transfer vector is a replication-deficient adenoviral vector. This claim has an identical scope to that of claims 15, claiming the gene transfer vector of claim 14, wherein the adenoviral vector is replication-deficient, wherein claim 14 specifies the gene transfer vector of 13 wherein the viral vector is an adenoviral vector, and wherein claim 13 specifies the gene transfer vector of claim 1 is a viral vector.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 and 13-21, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, have been amended to no longer recite "codons expressed more frequently in humans". Therefore, the rejection is withdrawn.

NEW 112, 2nd paragraph rejection

6. Claims 1, 6-10, and 13-21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 recited comprises a nucleic acid and a heterologous sorting signal, "wherein the nucleic acid sequence comprises SEQ ID NO:1." The metes and bounds of this recitation are indefinite because it is not clear if the heterologous sorting signal is in addition to the processing and sorting signal already encompassed in SEQ ID NO:1 or if the heterologous sorting signal is in addition to SEQ ID NO:1.

Claims 6-10 and 13-21 depend from claim 1, which has been deemed indefinite. Therefore, dependent claims 6-10 and 13-21 are rendered indefinite.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-10 and 13-21, rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al. (1999, of record), Wu et al (1995; of record), Farina et al (2001, of record), Mogridge et al (2001; of record), and Hamdan et al (Parasitol Res. 88:583-586, June 2002), have been amended and no longer are made obvious by the art. Therefore the rejection is withdrawn.

Applicant traverses this rejection on the grounds that the *prima facie* case was made in hindsight of the specification and that the amendments to the claims overcome this rejection.

Applicant's arguments are only partially persuasive. It is acknowledged that many of the references of this rejection were present in the specification. However,

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each of these arts taught why each of the components would optimize the vector and provided motivation for combining the references independent of the specification.

However, the amendment to the claims to recite the nucleic acid of SEQ ID NO:1 is free of the art and therefore, is no motivation for the specific sequence of SEQ ID NO:1.

Therefore, the rejection is withdrawn.

Conclusion

8. SEQ ID NO:1 is free of the art and encompass allowable subject matter.

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble

Joe W. W. W.
AV16 Br